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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,501	01/10/2006	Ronald W Wood	176/61373	5801

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,501	WOOD, RONALD W	
	Examiner	Art Unit	
	Brian-Yong S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *7-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/01/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application

1. Acknowledgement is made of applicant's amendment/remarks filed on 10/01/2009. By the amendment, claim 1 has been amended and claims 24-27 have been newly added.

Applicant stated in the response that claims 7-23 have been withdrawn from further consideration as being drawn to non-elected species. However, further reviewing of the previous office action mailed 04/01/2009 and Response filed 02/25/2009, only claims 2-5 and 7-21 were withdrawn from further consideration as being drawn to non-elected invention based on the applicant's statement that "Claims of Group A reading on the elected species include claims 1, 6, 22 and 23" (see Applicant's election filed 02/25/2009). Applicant is requested to clarify on this issue. If applicant believes that applicant made an error in identifying claims 22 and 23 as group of claims that read on the elected species, applicant should specifically point out the supposed error(s) in the applicant's election and request to the instant examiner for necessary corrections in the prosecution record. In absence of such statement or remarks, claims 22 and 23 are continuously considered as the elected invention and examined accordingly.

Acknowledgement is made of applicant's remark that claims 2-5, which were not included in the applicant's original election (due to a supposed error of the applicant), are believed to read on the elected species. Applicant requests that claims 2-5 should be rejoined and examined to the extent that they read on the elected invention. Accordingly, claims 2-5 will be included and examined for prosecution on the merits of the case.

2. Above mentioned applicant's request and the amendment, requiring "intravesically", "the prolonged duration of action...", "an additive selected from the group consisting of carboxymethyl cellulose..." and "condition selected from the group consisting of urge

incontinence…" recited in claims 1 and 24-27 respectively, necessitated a new ground of rejection in this Office Action.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites that the pharmaceutical composition further comprises additive such as "heparin-like compounds". Claim 11 is vague and unclear and leaves the reader in doubt as to the meaning or "metes and bounds" of the invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim1-6 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bannister et al. (WO 02/45711 A1), and further in view of Wood (US 6482837).

Bannister teaches a use of anti-muscarinic agent (i.e., tiotropium which is also commonly known as tiotropium bromide or Ba 679BR) in combination with calcium channel blocker for the treatment of a muscle tone disorder or a proliferative, inflammatory or secretory condition including urinary incontinence, preferably in oral route (see abstract and the disclosure of WO'711, especially page 4, lines 1-6 and 11-16; page 5, lines 19-23; claims 12-13 and 17).

Wood is being provided as a supplemental reference to demonstrate the state of art knowledge at the time of the invention was made that the intravesical delivery of antimuscarinic

agent provides advantage in treating bladder disease such as urinary incontinence including urge incontinence because the adverse effects associated with oral administration of antimuscarinic or anticholinergic agent could be minimized by administration of the antimuscarinic or anticholinergic agent via intravescial instillation (abstract; column 1, lines 20-24; column 5, lines 52-58; column 12, lines 9-60; column 15, lines 22-43). Wood also teaches that the additive (e.g., sodium carboxymethyl cellulose, heparin and pentosan) is useful in formulating solution or suspension which is intended for intravesical delivery because such additive prolong the drug's action or improve the time course of its contact with the bladder which is desirable (column 35, lines 22-42).

The teaching of Bannister mainly differs from the instant invention in the delivery of said composition intravesically. Furthermore, the teaching of Bannister differs from the instant invention in (ii) the formulation of said composition to have "a prolonged duration of action", namely at least about three weeks, (iii) the incorporation of an additive (e.g., carboxymethyl cellulose, glycosaminoglycans, pentosan polysulfate, heparin, and heparin-like compounds) and (iv) the subject having condition selected from the group consisting of "urge incontinence, cystitis, bladder dysfunction of multiple sclerosis, benign prostate hyperplasia, myelomeningocele, spinal cord injury, dementia…and inability to tolerate systemic effects of antimuscarinic medications"

However, there are general references, for example US'837, indicating that pharmaceuticals generally may be delivered intravesically, as well as disclosing benefits to be achieved by intravesical versus other modes of administration, e.g., systemic. Therefore, there exist general art accepted motivations for formulating drugs for intravesical administration. One

would have been motivated to make such modification to increase the efficacy (e.g. solubility, compatibility, etc) in treating patient suffering from urinary incontinence or urge incontinence and extend the usage of antimuscarinic agent such as tiotropium containing composition by making the formulation having prolonged duration of action, which is intended for intravesical delivery, to meet patient's preference and needs where the adverse effects associated with system administration of antimuscarinic agent could be minimized. Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Since the interpretation of the instant transition term "comprising" allows for the inclusion of unspecified ingredients even in major amounts or additional steps, the references in combination make obvious the instant invention.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614